

CLAIMS

1. A microemulsion pre-concentrate comprising a difficultly soluble active agent and a carrier medium comprising

- 5           1) a hydrophilic phase which comprises dimethylisosorbide and/or a lower alkyl alkanoic ester,  
             2) a lipophilic phase, and  
             3) a surfactant.

2. A composition of claim 1 wherein the active agent is a cyclosporin or a macrolide.

10           3. A composition as claimed in claim 1 or claim 2, wherein the active agent is selected from Cyclosporin A, rapamycin, 40-O-(2-hydroxy)ethyl rapamycin, 33-epi-chloro-33-desoxy-ascosomycin, FK 506 or ascomycin.

15           4. A composition as claimed in any preceding claim wherein the hydrophilic phase comprises ethyl acetate as lower alkyl alkanoic ester.

5. A composition as claimed in one of claims 1 to 4 for oral or parenteral administration.

15           6. A pharmaceutical composition for enteral or parenteral administration comprising a macrolide and an acid.

7. A composition as claimed in claim 6 wherein the acid is a mono-, di- or tri-carboxylic acid.

20           8. A composition as claimed in claim 6 or claim 7 wherein the acid is selected from malonic acid, oxalic acid, citric acid and lactic acid.

9. Use of an acid to stabilise a macrolide in a pharmaceutical composition.

10. A method of stabilising a macrolide in a pharmaceutical composition, which method comprises mixing an acid with the macrolide.